

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	9 th April 2015
Appraisal & Details	<p>Aripiprazole (Abilify Maintena®, Otsuka Pharmaceuticals) long acting injection for schizophrenia</p> <p>The Northern (NHS) Treatment Advisory Group considered an appraisal on the use of aripiprazole long acting injection (LAI) within its licensed indication for the treatment of schizophrenia.</p>
Recommendation	<p>The Northern (NHS) Treatment Advisory Group recommends the use of aripiprazole as per its licensed indication and as outlined in <i>the Guidance on the Use of Antipsychotic Long-acting Injections in the North of England</i>.</p> <p>Aripiprazole LAI was found to be non-inferior to oral aripiprazole for the prevention of relapse of schizophrenia after twenty-six weeks treatment in the licensed population. A second study found it was superior to placebo for the same outcome, although the trial was terminated early on ethical grounds, to limit patient exposure to placebo.</p>
Clinical evidence summary	<p>A pivotal phase III trial (n=662) found that aripiprazole LAI was non-inferior to oral aripiprazole for the primary outcome of impending relapse after 26 weeks treatment. A second trial showed that it was superior to placebo.</p> <p>There is currently no published data comparing aripiprazole prolonged release injection with other antipsychotics (oral or injectable).</p>
Safety	<p>The EMA has reported pooled safety data from 1600 patients exposed to aripiprazole LAI, approximately 1000 of whom were exposed for at least 6 months. No new safety concerns were identified compared to oral or rapid intramuscular formulations of aripiprazole. The exception was injection site pain, which was reported by 5.2% of patients receiving aripiprazole 400 mg LAI, compared to 0.8% receiving the 50 mg pseudo-placebo and 3.7% receiving true placebo. The incidence of extra-pyramidal symptoms was higher with the 400 mg LAI than oral aripiprazole, and a post-authorisation study has been requested. While the incidence of weight gain was comparable between groups, clinically significant weight loss was more common with the 400 mg LAI than oral aripiprazole.</p>
Patient Perspective	<p>Aripiprazole has a more favourable adverse event profile than the other second-generation antipsychotics with available depot formulations, including a lower risk of weight gain. While this may be appealing to patients, the product is only licensed in people already stable on oral aripiprazole and switching may not be appropriate. In addition the monthly administration of aripiprazole may be more convenient.</p>
Cost analysis summary	<p>The acquisition cost for aripiprazole LAI is lower than the other licensed depot preparations. Aripiprazole LAI costs less than most other atypical antipsychotic depots but more expensive than oral aripiprazole. A summary of cost-effectiveness published by the SMC found that, taking into account administration costs, aripiprazole LAI was cheaper than both risperidone and paliperidone during both the initiation and maintenance phases.</p> <p>However administration costs will vary depending on the setting, and will be higher for preparations requiring more frequent injections.</p>
Financial impact	<p>If used as outlined in the guidance the financial impact of this recommendation is expected to be low.</p>
PbR: NA	